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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,258	09/25/2003	Robert O. Williams	10071-037-999	3229

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EXAMINER	
ROYDS, LESLIE A	
ART UNIT	PAPER NUMBER
1614	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	01/10/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/669,258	WILLIAMS ET AL.	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-57 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-57 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-57 are presented for examination.

Requirement for Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-23, drawn to an emulsion or patch comprising an emulsion comprising an antidepressant, an NMDA receptor antagonist, a lipophilic component, water and a surfactant, classified in class 424, subclasses 401, 443 or 449, for example.

II. Claims 24-40, drawn to a method for treating pain comprising topically administering to the skin of a mammal in need thereof an emulsion comprising an antidepressant, an NMDA receptor antagonist, a lipophilic component, water and a surfactant, classified in class 424, subclasses 401, 443 or 449, for example.

III. Claims 41-57, drawn to a method for inducing local anesthesia comprising topically administering to the skin of a mammal in need thereof an emulsion comprising an antidepressant, an NMDA receptor antagonist, a lipophilic component, water and a surfactant, classified in class 424, subclasses 401, 443 or 449, for example.

The inventions are distinct, each from the other, for the following reasons:

Inventions I and Inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the product as claimed can be used in a materially different process of using that product, namely, for treating fibromyalgia.

Inventions II and III are directed to related processes. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design,

mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j).

In particular, Inventions II and III are related because they recite the topical administration of an emulsion comprising an antidepressant, an NMDA receptor antagonist, a lipophilic component, water and a surfactant to a patient in need thereof. However, Invention II is directed to a method for treating pain, wherein the amount of the emulsion is effective to achieve such an objective. The method of Invention III is directed to a method for inducing local anesthesia, wherein the amount of the emulsion is effective to achieve such an objective. Accordingly, the processes of Inventions II and III clearly have different functions and/or effects. It is additionally noted that the treatment of pain does not necessarily result in the complete induction of local anesthesia at the site of application.

Further, Inventions II and III comprise steps that are not required for any other method. Invention II requires the application of the emulsion in an amount effective to treat pain. Invention III requires the application of the emulsion in an amount effective to induce local anesthesia. In other words, the amounts required to achieve each objective are distinct and unique to the desired objective.

Accordingly, the modes of operation, functions and/or effects of the methods are clearly distinct from one another, despite the fact that the Inventions are related solely on the basis of the topical application of an emulsion comprising an antidepressant, an NMDA receptor antagonist, a lipophilic component, water and a surfactant. In view of the fact that the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants, the inventions are properly held to be patentably distinct from one another.

Because these inventions are distinct for the reasons given above, they require a different field of search (see MPEP § 808.02) and they have acquired a separate status in the art because of their recognized divergent subject matter, the requirement for election for examination purposes as indicated is proper.

Election of Species Requirement

This application contains claims directed to patentably distinct species of (i) antidepressant, (ii) NMDA receptor antagonist, (iii) lipophilic component and (iv) surfactant (claims 1-57).

The species are independent or distinct because the species of antidepressants, NMDA receptor antagonists, lipophilic components and surfactants recited in the present claims are structurally and/or chemically distinct from any one other of the respective components encompassed by the present claims such that a comprehensive search of the patent and non-patent literature for, for example, any one such antidepressant would not necessarily result in a comprehensive search of any one or more or all of the other antidepressants encompassed by the claims. Similar reasoning applies equally to the chemically and structurally distinct NMDA receptor antagonists, lipophilic components and surfactants encompassed by the present claims, but for the obvious difference in the type of compound. It remains that, though Applicant has discovered that this generic combination of agents is amenable for use in treating pain or inducing local anesthesia, the art may have recognized a different advantage or benefit to any one or more of these combination(s) of compounds that differs from the advantage that Applicant has discovered and, thus, the search for any one combination would not necessarily encompass a comprehensive search for any one other combination presently claimed. Furthermore, the disparate nature and variability encompassed by these broad genera of compounds precludes a quality examination on the merits not only because a burdensome search would be required for the entire scope of the claim(s), but also because consideration of the findings of such a search for compliance with the statutes and requirements set forth under 35 U.S.C. 101, 102, 103 and 112 would be unduly onerous.

Election of species should be made consistent with the following instructions:

Election of any one of Groups I, II or III requires the election of a **single disclosed specie** of (i) antidepressant, (ii) NMDA receptor antagonist, (iii) lipophilic component and (iv) surfactant.

Election of any one single disclosed specie of antidepressant may be made from those

antidepressants specifically claimed (see, e.g., claims 4-8, 27-31 or 44-48) **or** a generic antidepressant not specifically claimed in present claims 4-8, 27-31 or 44-48.

Election of any one single disclosed specie of NMDA receptor antagonist may be made from those specifically claimed (see, e.g., claims 12-13, 35-36 or 52-53) **or** a generic NMDA receptor antagonist not specifically claimed in present claims 12-13, 35-36 or 52-53.

Election of any one single disclosed specie of lipophilic component may be made from those specifically claimed (see, e.g., claims 16 or 18) **or** a generic lipophilic component not specifically claimed in present claims 16 or 18.

Election of any one single disclosed species of surfactant may be made from those listed at page 18, line 20-page 19, line 23.

Applicant is also advised that a proper reply to the present requirement will also indicate whether Applicant intends to elect an emulsion that further comprises a lipophilic intradermal penetration enhancer and/or a humectant and/or an anti-foaming agent.

In the event that Applicant **elects an emulsion that further comprises a lipophilic intradermal penetration enhancer**, election of a single disclosed species of lipophilic intradermal penetration enhancer is required and may be made from those specifically claimed (see, e.g., claims 20, 40 or 57) **or** a generic lipophilic intradermal penetration enhancer not specifically claimed in present claims 20, 40 or 57.

In the event that Applicant **elects an emulsion that further comprises a humectant**, election of a single disclosed species of humectant is required and may be made from those listed at page 20, lines 28-31.

In the event that Applicant **elects an emulsion that further comprises an anti-foaming agent**, election of a single disclosed species of anti-foaming agent is required and may be made from those listed at page 20, lines 19-20.

Applicant is cautioned that the election of a particular specie of antidepressant, NMDA receptor antagonist, lipophilic component, surfactant, and, if applicable, a lipophilic intradermal penetration enhancer, humectant, or anti-foaming agent, wherein the elected specie(s) is/are not adequately supported by the accompanying specification, may raise an issue of new matter under the written description requirement of 35 U.S.C. 112, first paragraph.

Currently, claims 1-57 are generic.

Applicant is advised that a reply to this requirement must include an identification of the single disclosed species of antidepressant, NMDA receptor antagonist, lipophilic component, surfactant, and, if applicable, a lipophilic intradermal penetration enhancer, humectant, or anti-foaming agent, that is elected consonant with this requirement and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, Applicant must indicate which are readable upon the elected species. Please reference MPEP §809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though this requirement be traversed (37 C.F.R. 1.143) and (ii) an identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should Applicant traverse on the ground that the inventions or species are not patentably distinct,

Applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The Examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP §821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 C.F.R. 1.116; amendments submitted after allowance are governed by 37 C.F.R. 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 C.F.R. 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. §103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicants are advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP §804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Leslie A. Royds
Patent Examiner
Art Unit 1614

January 3, 2007

Ardin H. Marschel 1/4/07
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER